Topic: **Traditional 510K for *Horizon XVu– addition of FFR***
Programmable diagnostic computer

Establishment Name, Registration Number and Address:

510K number:	K123792
Name:	Mennen Medical Ltd.
Registration Number:	9611022
Operator Number:	9069173
Address:	4 Hayarden Street, Yavne, 81228, Israel
Postal Address:	PO Box 102, Rehovot, 76100, Israel
Tel:	+972-8-9323333
Fax:	+972-8-9328510
Contact person:	Ifat Oren, Regulatory Affairs

To: Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

AUG 3 0 2013

Attn.: Document Control Clerk
From: Ifat Shwarts, Regulatory Affairs

The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name	Programmable diagnostic computer
2. Classification Number:	21 CFR 870.1425
3. Common/Usual Name	Programmable diagnostic computer
4. Trade/Proprietary Name	Horizon XVu
5. Part Number of *Horizon SE*	960-100-310 (115V) 960-100-320 (230V)
6. Establishment Registration Number	9611022
7. FDA Classification	Class II
8. Product Code	DQK
9. Reviewing Panel	Cardiovascular
10. Performance Standards	page 12
11. 510(k) Marketing clearance for Horizon XVu	K091165 – August 7, 2009

ComboMap

Traditional 510(k): Device Modification – Horizon XVu K123792

Terminology

Subject of this 510(k) = Horizon XVu with FFR
The Horizon XVu is a modified device, a system identical to the Horizon XVu Cathlab with the addition of Fractional Flow Ratio (FFR) measurement.

This submission is for a modification of the Horizon XVu that Mennen Medical has received 510K clearance for marketing by the FDA (K091165) August 7, 2009 (enclosed in part 21)

We intend to add to the Horizon XVu Computerized Catheterization Laboratory, FFR measurement option using as a predicated device the:

Volcano ComboMap = The predicated device for FFR measurement. The COMMBOMAP was cleared for marketing by FDA (K041134) June 2, 2004 (see attached FDA letter – part 21)

Intended Use of the Horizon XVu with FFR

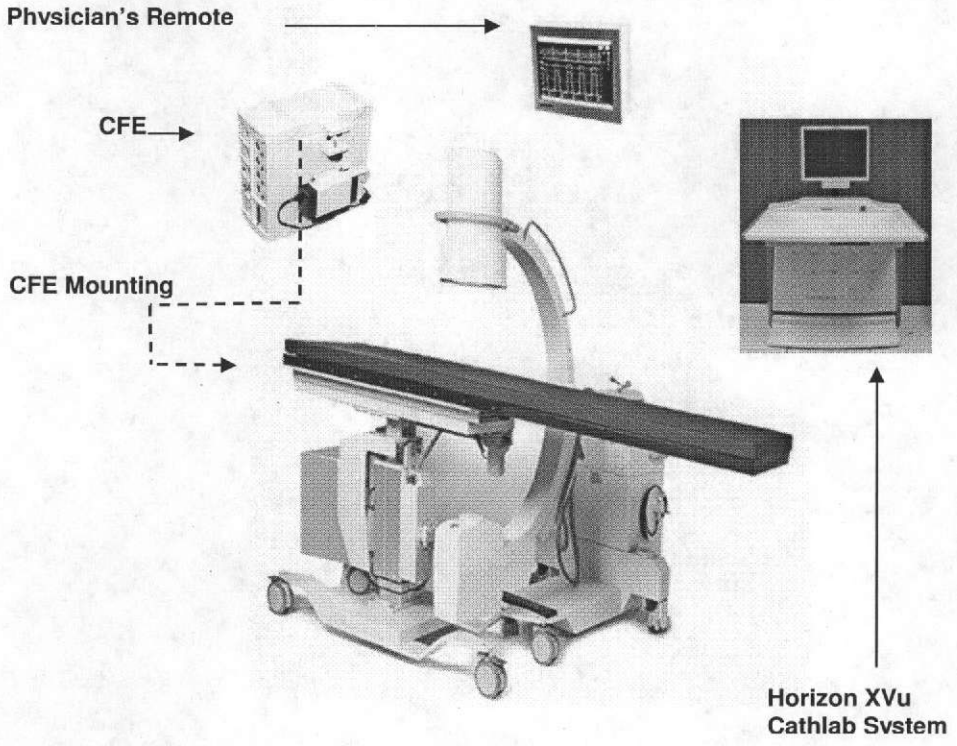
The Horizon XVu is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, Intra Cardiac ECG (ICECG), invasive blood pressures, pulse oximetry, respiration, cardiac output, body temperatures and EtCO2.

Heart rate, multi-lead ECG and BP waveforms from different heart sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, and FFR waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

1. Device Description: Horizon XVu

The prime function of the Horizon XVu (Cathlab) is to acquire and display vital-sign data and waveforms in real time during the catheterization process, creating a fully documented case history.

Horizon XVu System (Console option) – General View



2. Functional Description of the Horizon XVu

The Horizon XVu is capable of acquiring and displaying essential patient data such as ECG/Heart Rate, ICECG, invasive blood pressures, pulse oximetry, respiration, cardiac output, and body temperature. Heart rate, multi-lead ECG, EtCO2 and BP waveforms from different heart and vascular sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

The Horizon XVu software includes graphic presentation of the Heart and abdominal, cranial and peripheral vascular system, to support reporting of heart and vascular catheterization.

Catheterization procedure

During a typical catheterization procedure, the physician guides a catheter to the site of interest by observing an X-ray display and the Horizon XVu Patient Data Display, and then instructs the catheterization technician at the on-line workstation to acquire pressure waveform(s) data for that site. With a single keystroke, the technician labels the site and initiates waveform/data sample acquisition.

The waveform of interest changes to a pre-defined color at the Patient Data Display during acquisition for ease of identification. Another keystroke signals the Horizon XVu to stop the acquisition and begin analysis of the newly acquired pressure information via the dedicated Workstation Horizon XVu Computer, at which time the waveform for the corresponding pressure channel will change back to one of the default colors for non-defined pressures.

The Patient Data Procedure Display provides a view of the acquired ECG and heartbeats sampled for review, editing, and acceptance via the Horizon XVu Interface. The numerical results of calculations are based on the average of the accepted beats. These results will include such items as (for example) Systolic, Diastolic, and Mean pressure values.
The technician may at this point use the Interface to accept the displayed pressure information; doing so will store the values to the patient's on-line Procedure File.

The Horizon XVu is used for activities such as coronary and peripheral endovascular procedures and Angioplasty. The basic steps described above (catheter positioning, site definition/acquisition, analysis and acceptance) are performed as an integral part of these procedures.

The system has a computer that utilizes powerful, real-time, software to control the system operation and to process the vital patient sign data measurements acquired from the CFE or entered manually at the keyboard.

A Laser Printer is provided in the system. This provides printouts of textual and graphical summaries of all patient data and catheterization procedures.

Base Configuration: Cathlab parameters

- ECG/Heart Rate/Respiration
- 4 Invasive Blood Pressure channels
- Non-invasive Blood Pressure
- Pulse Oximetry (SpO_2)
- EtCO2 (optional)
- respiration
- temperature
- ICECG – Intra-Cardiac ECG

Horizon XVu Options:

- Full Disclosure
- Off-line workstations
- Remote Interactive terminal
- Angiography Analysis Package
- Fractional Flow Reserve - FFR
- CDR, DVD drive
- Choice of Console Table – regular, enhanced, compact or without consol

Main components of the Horizon XVu:
The Horizon XVu system consists of:

(A) a **Front End unit** and
(B) a **Central system**

(A) The "**Cathlab Patient Front End**" (CFE) acquires, processes, and converts vital signs from the patient into digital signals. The CFE then sends the digitized signals and data, via a network connection, to the central system of the Horizon XVu for process and display.

The CFE can acquire the following physiological signals of the patient:

- ECG – the CFE acquires an ECG waveform and measures Heart Rate
- ICECG - the CFE measures 6 channels of differential intra-cardiac ECG
- Blood Pressure – the CFE acquires a BP waveform and measures Systole, Diastole and Mean Pressure
- Temperature – the CFE measures Temperature by means of a numeric value in C° or F°
- SpO_2 – the CFE acquires and measures oxygen saturation and creates a photoplethysmographic waveform and numeric value of the oxygen saturation
- EtCO2 – the CFE measures CO2 during the respiration cycle and present the end tidal (end expiratory) CO2 and the inspired CO2 - inCO2 and the respiration rate - RR

(B) The **Central System** contains the following main devices:

- Computer– see details below
- Two local LCD displays
- Video line driver
- AC Power Unit
- Laser printer
- Hub
- Modem

FFR – Fractional Flow Reserve

FFR is a mode that uses two invasive pressure inputs.
Pa – Proximal pressure measured with external pressure transducer at the artery or aorta. and
Pd – Distal pressure measured with a pressure wire sensor in the coronary arteries across lesion.
Mean pressures are calculated and the ratio between the means Pd/Pa is calculated and displayed. The value of Pd/Pa is calculated continuously during intracoronary or venous pharmacological Hyperemic stimulus. The pressure gradient across lesion is measured and the pressure ration is calculated. Providing the FFR parameter that is used to evaluate the importance of the lesion in limiting blood flow to the distal coronary.

Computer Workstation

The computer workstation is a uni-processor system that runs the Horizon XVu program on a UNIX operating system. The workstation receives the digitized signals from the CFE via the Ethernet hub, displays real-time vital signs, analyzes, processes, and calculates the vital sign data and waveforms, cardiac status in real time during the catheterization process, creating a fully documented case history. The workstation continuously displays the vital signs waveforms and data on the local LCD displays.

The hemodynamic data, ECG and FFR waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

3. **Horizon XVu** 960-OPT-580/585 – **similarity and Differences in Design**:

Horizon XVu with FFR 960-OPT-580/585 vs. Horizon XVu

The following technological and other characteristics/features apply to both the Horizon XVu and to the Horizon XVu with FFR 960-OPT-580/585

- Intended for use in hospitals
- Do not change the functionality of the Cathlab system
- Isolated inputs for vital signs sensors

- ECG amplifier front end with defibrillator protection
- Invasive BP input circuit
- Non Invasive BP measurement
- SpO2 measurement
- Selectable filters for ECG and BP
- Analog output for ECG and BP
- Doctor's display of vital signs and physiological waveforms
- Show doctor feature for diagrams from the technician screen

The main difference between the Horizon XVu and the Horizon XVu with FFR 960-OPT-580/585.:
On the Horizon XVu with FFR 960-OPT-580/585 it is possible to display the FFR waveform and value.

The SW changes of the Horizon XVu with FFR 960-OPT-580/585 vs. the Horizon XVu are not related to the type, size, method of integration, and assembly of the HW components.

The following table compares the major software element and/or changes done in the Horizon XVu vs. the Horizon XVu with FFR 960-OPT-580/585, Cathlab:

SW Component	**Horizon XVu** **960-800-XXX**	**Horizon XVu** with **960OPT**580/585 **FFR**
Doctors display	All waveforms and numeric vital sings	Same
Display of leads and waveforms on Cathlab display screen	Yes	Yes
Solaris Operating System for Cathlab	Yes	Yes
Technician Screen	Controls only	Same
GUI	Same	Same
Menus	Full set	Same
Vital Signs	Full set	Full set + FFR

	Horizon XVu	**Horizon XVu- FFR**
Part/Option Number	**960-800-XXX**	960-OPT-580 for use of RADI wire 960-OPT-585 for Volcano wire
Input Circuit Parameters		
Surface ECG	**Yes**	**Yes**

ICECG	**Yes**	**Yes**
NIBP	**Yes**	**Yes**
Invasive BP	**4 channels**	**4 channels – 2 used for FFR**
Respiration	**Yes**	**Yes**
SpO2	**Yes**	**Yes**
EtCO2	**Yes**	**Yes**

Menu Details

Technician Display

The technician display of the Horizon XVu FFR 960-OPT-580/585 is identical to the Horizon XVu with the addition of control of the FFR procedure.

The GUI control keys of the Horizon XVu 960-OPT-580/585 are same as to the Horizon XVu, with the addition of FFR procedure

We submit that the addition of the FFR 960-OPT-580/585 option to the Horizon XVu is limited to the addition of a new parameter – FFR. This change does not amount to a change in the "fundamental scientific technology" of the Cathlab and does not disqualify the Horizon XVu from being the subject of a 510(k).

Comparison to the predicate device

The Horizon XVu with FFR 960-OPT-580/585 option is comparable to the FFR mode of the predicated device Volcano – ComboMap (see also part 12- Substantial equivalence)
The functional menus of Horizon XVu were modified by adding the option to measure and calculate the FFR vital sign and waveform, without any change to the other vital sign monitoring capabilities

Subject	**Volcano – ComboMap Predicated Device**	**FFR mode on Horizon XVu**
FDA 510 K	K 041134	K 091165 prior to change
Features	FFR + Flow velocity	FFR
Pressure wire	Volcano	Volcano or Radi
Transducer input	5μV/V/mmHg	5μV/V/mmHg
Pressure range	–30 to +330 mmHg	-50 to +300 mmHg
Pressure bandwidth	DC to 25 Hz	DC to 6 Hz, DC to 12 Hz, **DC to 24 Hz,** DC to 40 Hz

Measurement accuracy	± 3 mmHg (–30 to +100 mmHg) ± 3% (> 100 mmHg)	+ /- 2 mmHg, or +/- 2%, whichever is greater, exclusive of transducer
# pressure channels	2	4 (2 used for FFR)
Analog Pressure output	1V/100 mmHg.	same
Pa	Mean Arterial Pressure	Same
Pd	Mean Distal Pressure at the tip of the pressure wire	Same
FFR = Pd/Pa	Ratio	Same
Tracing	ECG, Pa dynamic , Pa mean, Pd dynamic, Pd mean FFR	Same Same Same Same

Explanation of differences

The basic amplifier specifications are the same for the Horizon XVu (FDA approved) and the Horizon XVu with FFR

The number of pressure channels of the Horizon XVu is four (4). Two (2) of these channels are used for the FFR calculation. Same as in the predicated Volcano **ComboMap.**
The FFR option of the Horizon XVu is comparable only to the pressure measurement of the COMBOMAP, and not to the **ComboMap_** capabilities to measure flow.

4. Reasons to the change

FFR

Mennen Medical has added to the FFR capability, for the following reasons

- Users request to add to the Horizon XVu the FFR software capability to enable use of the pressure measurements that are performed in any case of hemodynamic catheterization.
- Use of FFR feature on the Horizon XVu provides an important measurement without the need for an addition device.
- The Horizon XVu is used for coronary diagnosis and implantation of stents and FFR is a diagnostic tool in the decision if and where to implant a stent.

We submit that no changes were made:

- to the control mechanism of the Horizon XVu.
- to the operating principle of the Horizon XVu.
- to the energy type of the Horizon XVu

The FFR option is a software option , thus sterilization is not an issue.

FFR capability uses single use pressure wire sensors not manufactured by Mennen Medical which are supplied sterile. Thus sterilization is not an issue.

5. Conclusion of comparison of technological characteristics:

We consider the FFR option of the Horizon XVu to be substantially Equivalent to the FFR in the Volcano **ComboMap**

We submit that any difference between the FFR measurement of the Horizon XVu and the FFR measurement of the **ComboMap**.

- fall within the scope of a 510(k) Device Modification and
- do not raise any new issues of safety and effectiveness

6. Verification, Validation and Testing

The Horizon XVu has been subject to extensive performance testing to ensure that:
1. The acquisition and display of the patient data and waveforms by the **Horizon XVu** with 960-OPT-580/585 remain the same for the predicate device Horizon XVu.

At the system level, SW Validation of the performance of the Horizon XVu with **960OPT**580/585 as compared to the Horizon XVu Cathlab system, was carried out in accordance with the test plan described in the Mennen Medical Validation Test Procedure for the Horizon XVu.

The SW Test Description for the Horizon XVu with **960OPT**580/585 was derived from the SW Test Description for the Horizon XVu Cathlab system, with the necessary addition of the FFR measurements

Final testing for the Horizon XVu system included performance tests designed to ensure that the device meets all functional requirements and performance specifications, in accordance with the requirements of the Final Test Procedure for the Horizon XVu system.
Electrical Safety testing and EMC testing were performed by an independent testing laboratory (Standard Institute of Israel SII) to ensure that the device complies to applicable industry and safety standards (attached in Part 17)

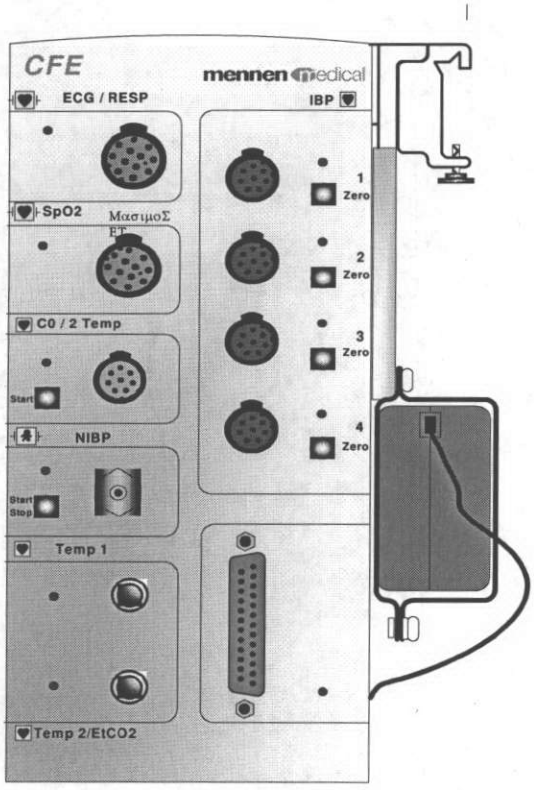
7. Proposed Labeling

The system will be called **Horizon XVu** with FFR **960OPT**580/585

Page IV of the introduction to the Horizon XVu User Guide contains the following

Prescription Notice: "Federal United States law restricts the sale and use of this instrument to qualified medical personnel only." The following symbols appear on page IX of the Horizon XVu User's Guides under the section entitled "Label Locations & Symbol Descriptions," and on the front panel of the CFE. See the image of the front panel of the CFE on page 11 below.

	"Attention – see Accompanying Instructions for Use"
	Type BF Applied part (next to NIBP, EtCO2 and SpO2 connectors)
	Type CF Applied Part (next to IBP, Temperature and CO connectors)
	Type CF Applied Part – Defibrillation Proof (next to ECG connector)



Symbols and labeling on the front panel of the CFE

8. Voluntary Standards

Appropriate voluntary standards for this device, to which conformance have been demonstrated:

- **IEC 60601-1:** (2005) Medical Electrical Equipment Part:1 General Requirements for Safety
- **IEC 60601-1-1** (2000) Medical Electrical Equipment Part 1-1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
- **IEC 60601-1-2** (2007): Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- **IEC 60601-2-27** (2005):
  Medical electrical equipment, Part 2,
  Requirements for safety of electrocardiograph monitoring equipment.
- **IEC 60601-2-30** (1999):
  Medical electrical equipment, Part 2 - requirements for safety of automatic cycling indirect blood pressure monitoring equipment
- **IEC 60601-2-34** (2005):
  Medical electrical equipment, Part 2 - Particular requirements for the safety of direct blood pressure monitoring equipment
- **IEC 60601-2-49** (2006):
  Particular Requirements for the safety of multifunction patient monitoring equipment

9. Indications for Use

The Horizon XVu is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, Intra Cardiac ECG (ICECG), invasive blood pressures, pulse oximetry, respiration, cardiac output, body temperatures and EtCO2.

Heart rate, multi-lead ECG and BP waveforms from different heart sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, and FFR waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

Attachment:

Horizon XVu User Manual – part 13
FTP for FFR option in Horizon XVu – Part 16 j
Horizon XVu, Risk Analysis – part 16 d

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 30, 2013

Mennen Medical Ltd.
c/o: Ifat Shwarts
Regulatory Affairs
4 Hayarden st., Yavne P.O. Box 102
Rehovot, IS 76100

Re: K123792
Trade Name: Horizon XVu (FFR)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQX
Dated: August 2, 2013
Received: August 5, 2013

Dear Ifat Shwarts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Horizon XVu**

Indications For Use:

The Horizon XVu is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, Intra Cardiac ECG (ICECG), invasive blood pressures, pulse oximetry, respiration, cardiac output, body temperatures, and EtCO2.

BP waveforms from different heart and vascular sites, are continuously presented on the Physiological Waveform Display. The hemodynamic data, waveform, gradients and FFR, can be stored, recorded, analyzed and presented in a variety of report formats.

*The Intended Use of the Horizon XVu as indicated above is same as the Indications For Use.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.08.30 15:27:18 -04'00'